

In re Appln. of PARIKH
Application No. 09/282,471

benzalkonium chloride, cetyltrimethylammonium bromide, chitosans and lauryldimethylbenzylammonium chloride, (e) colloidal clays such as bentonite and veegum or a combination thereof. A detailed description of these surfactants may be found in Remington's Pharmaceutical Sciences, and Theory and Practice of Industrial Pharmacy, Lachman et al, 1986.

IN THE CLAIMS:

Please cancel claims 32-50, without prejudice, and add the following new claims:

51. (New) A process of preparing fenofibrate microparticles in an aqueous medium comprising reducing the particle size of fenofibrate particles by sonication, homogenization, milling, microfluidization, precipitation, recrystallization, or a combination thereof, wherein

(1) prior to or during particle size reduction, the fenofibrate particles are mixed with (a) at least one natural or synthetic phospholipid and (b) at least one non-ionic, anionic, or cationic surfactant, and thereafter

(2) sufficient energy is applied to the mixture to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than that of fenofibrate particles produced without the presence of the surfactant using the same energy input.

52. (New) The process of claim 51, wherein the at least one surfactant is selected from the group consisting of casein, tragacanth, enteric resins, cholesterol esters, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, polyvinyl alcohol, polyvinylpyrrolidone, methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, sodium carboxymethylcellulose, calcium carboxymethylcellulose, potassium laurate, triethanolamine stearate, sodium lauryl sulfate, alkyl aryl polyether sulfonates, alkyl polyoxyethylene sulfate, sodium alginate, negatively charged glyceryl esters, sodium deoxycholate, dioctyl sodium sulfosuccinate, quaternary ammonium compounds, chitosans, colloidal clays, and combinations thereof.

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53. (New) The process of claim 51, wherein (a) the process comprises mixing the fenofibrate particles with at least two phospholipids and the at least one surfactant, (b) the process comprises mixing the fenofibrate particles with at least two surfactants and the at least one phospholipid, or (c) the process comprises mixing the fenofibrate particles with at least two phospholipids and at least two surfactants.

54. (New) The process of claim 52, wherein the at least one surfactant comprises a sorbitan fatty acid ester.

55. (New) The process of claim 54, wherein the at least one surfactant comprises a polyoxyethylene sorbitan fatty acid ester.

56. (New) The process of claim 52, wherein the quaternary ammonium compound is selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and combinations thereof.

57. (New) The process of claim 51, wherein the at least one phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, sphingomyelin, dimeyristoyl phosphatidylglycerol sodium salt, phosphatidic acid, lysophospholipids, and combinations thereof.

58. (New) The process of claim 51, wherein the fenofibrate particles are 5-100 μm in size.

59. (New) The process of claim 51, wherein the at least one surfactant comprises at least one surfactant in a concentration above its critical micelle concentration.

60. (New) The process of claim 51, wherein the process comprises preparing a pharmaceutically acceptable composition from the composition of fenofibrate microparticles.

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61. (New) The process of claim 60, wherein the process comprises drying the fenofibrate microparticles in the presence of a stabilizing agent.

62. (New) The process of claim 61, wherein the stabilizing agent is mannitol.

63. (New) The process of claim 60, wherein the process comprises preparing a suspension of the fenofibrate microparticles.

64. (New) The process of claim 60, wherein the process comprises preparing a powder from the composition by lyophilization, fluid drying, or spray drying.

65. (New) The process of claim 64, wherein the process comprises preparing an orally administrable~~gel~~ capsule comprising the powder.

66. (New) The process of claim 64, wherein the process comprises preparing an orally administrable granule from the powder.

67. (New) The process of claim 64, wherein the process comprises preparing an orally administrable tablet from the powder.

68. (New) The process of claim 64, wherein the composition is spray or fluid dried and the surfactant consists of polyvinylpyrrolidone or a combination of polyvinylpyrrolidone and at least one additional surfactant.

69. (New) The process of claim 68, wherein the at least one additional surfactant is sodium lauryl sulfate.

70. (New) The process of claim 68, wherein the composition is further converted into granules.

71. (New) A composition comprising fenofibrate microparticles produced by the process of claim 51.

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72. (New) A pharmaceutically acceptable composition comprising granules produced by the process of claim 70.

73. (New) The process of claim 51, wherein the at least one phospholipid is selected from the group consisting of egg phospholipid, soybean phospholipid, and combinations thereof.

74. (New) The process of claim 51, wherein the at least one phospholipid is partially or fully hydrogenated.